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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/890,284 | 08/13/2001 | Kazutaka Inoue | | 5139 |

7590 09/10/2003

Law Office of Townsend & Banta
601 Pennsylvania Avenue NW
Suite 900 South Building
Washington, DC 20004

EXAMINER

LAM, ANN Y

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1641

DATE MAILED: 09/10/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/890,284

Applicant(s)

INOUE ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Flower, 5,830,175.

As to claims 1 and 4, Flower discloses a first means having a detection circuit for detecting a residual voltage developed in the transdermal or the transmucosal, see column 5, lines 6-38; and second means (12) for determining a conduction state of current into the transdermal or the transmucosal based on the output detected by the first means, see column 7, lines 55-67.

As to claims 3 and 6, the residual voltage includes a discharging resistor (70) coupled between output terminals.

As to claim 7, Flower discloses an apparatus comprising a preparation for iontophoresis, see column 3, line 24, holding a drug, see column 4, line 11; and a device having means for generating an electrical output to supply a drug for the preparation into transdermal or transmucosal, see column 4, lines 56-63, and means for

Art Unit: 1641

detecting a reactive current flowing through the transdermal or the transmucosal and/or a residual voltage developed in the transdermal or the transmucosal to determine a conduction state of a current flowing into the transdermal or the transmucosal, see column 5, lines 6-23, and column 6, lines 23-26.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by McNichols et al., 5,047,007.

As to claims 1, 4 and 7, McNichols et al. disclose a first means having a detection circuit for detecting a reactive current flowing through a capacity component of impedance of the transdermal or the transmucosal and/or a detection circuit for detecting a residual voltage developed in the transdermal or the transmucosal, (see column 10, lines 25-31), and second means (i.e., sensor-feedback means) for determining a conduction state of current into the transdermal or the transmucosal based on the output detected by the first means, see column 9, lines 30-50, and column 10, lines 25-31.

As to claims 2 and 5, the detection circuit for detecting the reactive current includes a resistor coupled to an output terminal, a switch for sending one of positive and negative waveforms of current from the resistor, and a capacitor for smoothing out the current waveform from the switch, see column 14, lines 11-51.

As to claims 3 and 6, the residual voltage includes a discharging resistor coupled between output terminals, see column 14, lines 28-43.

As to claim 7, a device (10) for iontophoresis is disclosed.

Response to Arguments

Applicant argues that resistor (70) in the Flower reference does not include a detection circuit for detecting a residual voltage, however, Examiner asserts the contrary, see column 5, lines 6-11 and lines 36-38 in Flower, which discloses that controller (12) monitors the voltage drop at resistor (70), and that the device will indicate whether the system is operating and whether a used patch is connected or an inappropriate patch is connected.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mori et al., 6,141,582, discloses an iontophoresis system with a current detection device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

September 7, 2003

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detecting a reactive current flowing through the transdermal or the transmucosal and/or a residual voltage developed in the transdermal or the transmucosal to determine a conduction state of a current flowing into the transdermal or the transmucosal, see column 5, lines 6-23, and column 6, lines 23-26.

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September 7, 2003



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09/08/03